UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

HUMANA INC.,

Plaintiff,

v.

REGENERON PHARMACEUTICALS, INC.,

Defendant.

Case No. 7:21-cv-6245 (VB)

MEMORANDUM OF LAW IN SUPPORT OF REGENERON'S MOTION TO DISMISS OR STAY

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Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron") submits this memorandum in support of its motion, pursuant to Rules 12(b)(6) and 9(b), Fed. R. Civ. P., to dismiss the complaint (the "Complaint") of plaintiff Humana Inc. ("Humana"), or to stay this litigation pending the resolution of the earlier-filed action (the "DOJ Action") commenced by the U.S. Department of Justice ("DOJ") and based upon substantially similar allegations.

PRELIMINARY STATEMENT

Humana's claims should be dismissed in their entirety. All are based on alleged conduct that occurred six or more years before the Complaint was filed, and of which Humana was on notice for years before it commenced this action. They are accordingly time-barred and should be dismissed. Humana's claims should be dismissed for the further reason that the Complaint does not show that Regeneron, a leading biotechnology firm, engaged in racketeering or is liable on any of the multiple other inapplicable legal theories that Humana strains to invoke.

This case arises from Regeneron's donations to an independent charity, the Chronic Disease Fund ("CDF"). CDF helps low-income Medicare patients satisfy their copay obligations on pharmaceuticals to insurers such as Humana. Among the pharmaceuticals for which CDF provides such copay assistance is Regeneron's drug EYLEA® (aflibercept) Injection ("EYLEA"). EYLEA is an FDA-approved treatment for wet age-related macular degeneration ("wet AMD"), a leading cause of blindness in seniors.

Nothing is wrong with any of this. Physicians independently choose to prescribe EYLEA to their patients. Federal law permits charitable organizations like CDF to provide copay assistance, and permits pharmaceutical companies like Regeneron to contribute to such charities. Regeneron publicly disclosed that it made such contributions. And Humana's own policies permit insureds to seek copay assistance from charities such as CDF.

Humana claims that Regeneron engaged in a conspiracy with CDF and is accordingly

liable for the funds Humana spent to reimburse its policyholders for EYLEA. It alleges, purportedly in support of this claim, that in 2013 and January 2014—more than six and a half years before Humana commenced this action—Regeneron employees received projections from CDF of the dollar amount CDF expected to spend assisting EYLEA patients in those years, and that these projections allowed Regeneron to tailor its contributions to those projections in those years. Humana alleges that, had it known this, it would have denied coverage for insureds who received assistance from CDF. Humana nowhere alleges, however, that Regeneron influenced or controlled the manner in which CDF used its contributions, or that use of EYLEA by its policyholders to treat wet AMD was medically unnecessary. Humana's claim that Regeneron is somehow responsible for the amounts Humana spent to reimburse policyholders for EYLEA also rests on an attenuated and speculative causal chain, including the exercise of independent medical judgment by doctors in diagnosing, prescribing, and providing their patients with EYLEA rather than its more expensive or off-label alternatives.

For several reasons, Humana's nearly 70-page Complaint fails to state a claim.

First, Humana's claims are untimely. The alleged misconduct on which they rest—Regeneron's receipt of CDF's purported projections in 2013 and January 2014—occurred more than six years before Humana commenced this action, well-outside the relevant limitations period. Humana's conclusory allegation that Regeneron's conduct "commenced in mid-2012 and continued for years thereafter to the present," Complaint ¶ 250 (hereinafter "¶ _"), does not adequately plead misconduct within the limitations period. The claims are also untimely because Humana was on inquiry notice of these allegations for years before it asserted them. Humana had such notice based upon widely publicized investigations of contributions by multiple pharmaceutical manufacturers to CDF and similar charitable funds—matters that Humana

concedes were "like the one described in this Complaint," ¶ 173. Indeed, Regeneron disclosed in early 2017 that DOJ was conducting an investigation of Regeneron for the very matters at issue. Humana, as one of the world's largest health insurers, cannot have been unaware of these investigations, and does not claim that it was. Humana's attempts to invoke the "continuing violation" and "discovery rule" doctrines do not salvage its untimely claims.

Second, Humana stretches to transmute its allegations into claims under RICO—the "thermonuclear device" of civil litigation. *See Cedar Swamp Holdings, Inc.* v. *Zaman*, 487 F. Supp. 2d 444, 449 (S.D.N.Y. 2007). But this effort is baseless. The Complaint does not plead facts showing that Regeneron and CDF—independent organizations that operated at arm's length—constituted a RICO "enterprise." Nor does it plead a pattern of racketeering activity, another essential element of a RICO claim. Nor, finally, does the Complaint plead that the alleged conduct proximately caused Humana's purported damages. Humana's claims rest on an attenuated causal chain and a series of implausible counterfactual assumptions, including that doctors, had they not prescribed EYLEA to Humana's insureds, would have prescribed an off-label (and potentially risky) treatment.

Third, Humana's remaining state-law claims fail to plead causes of action. Its fraud and insurance fraud claims fail because the Complaint does not allege any false statements by Regeneron, that Humana relied on such statements, or that they were material. Nor does the Complaint plead facts showing that Regeneron had any duty to disclose the details of its relationship with CDF. Humana's claims for tortious interference with contract fail because they are predicated on the allegation that Humana's policyholders violated its policies by obtaining copay assistance—an allegation squarely refuted by the Humana policy document annexed to the Complaint. Humana's claims under state consumer protection laws fail because Humana is not a

consumer. Finally, Humana alleges no facts supporting its claim for unjust enrichment.

Alternatively, the Court should exercise its discretion to stay this action pending a resolution of the DOJ Action. Both cases arise from the same alleged conduct by Regeneron and CDF. The DOJ Action is being actively litigated and is far more advanced: a motion to dismiss has been fully briefed and decided, fact discovery is scheduled to be completed in January, and summary judgment motions will be filed in approximately nine months. Allowing both cases to be litigated at the same time would impose large, unnecessary costs on Regeneron and waste judicial resources. Humana would not be prejudiced by a stay. Mere delay is not prejudicial, as this Court has held. Any claim of prejudice by Humana is belied by its own delay in bringing this case, more than four and a half years after notice of the DOJ's investigation and more than a year after the DOJ Action was commenced.

STATEMENT OF FACTS

I. The Parties

Regeneron is a science-based, patient-focused biopharmaceutical company committed to developing new medicines for people with serious and rare diseases. After its founding in 1988, Regeneron spent twenty years and $1.3 billion conducting research before bringing its first drug to market in 2008. Regeneron has developed nine medications approved by the U.S. Food and Drug Administration ("FDA"), including EYLEA. Among other breakthroughs, Regeneron has developed the leading treatment to combat Ebola, and recently received Emergency Use Authorization for its COVID-19 antibody treatment. Regeneron's executive leadership team is led by physicians and scientists, and its Board consists of leading scientists and industry experts, including members of the National Academy of Sciences and Nobel Laureates. *See* Declaration of Jonathan H. Hurwitz, Ex. 6 at 14. (Exhibits to the Hurwitz Declaration are referred to hereinafter as "Ex. _.")

Humana is a nationwide health insurance conglomerate with "at least one type of Medicare plan in all 50 states." Ex. 7 at 6. In the second quarter of 2021, Humana reported projected annual consolidated revenue of more than $80 billion. Humana receives 68% of its 2020 premiums and service revenues from Individual Medicare Advantage plans. Ex. 8 at 20, 31.

At issue here are policies that Humana offers under Medicare Advantage, also called Medicare Part C. ¶ 43. Private insurers such as Humana—which is the "second largest sponsor of these Medicare plans in the United States"—offer Medicare Advantage plans to Medicare-eligible persons as an alternative to traditional Medicare. ¶ 43. As of June 30, 2021, Humana claimed to have 4.34 million individual Medicare Advantage members. Ex. 8.

II. Regeneron's Development of EYLEA

EYLEA is an ophthalmic injection approved by the FDA in 2011 to treat wet AMD, a chronic eye disorder that is a leading cause of blindness in the elderly. ¶¶ 20–21. Another drug approved by the FDA for wet AMD is Lucentis, manufactured by Genentech. ¶ 24. Since EYLEA was approved in 2011, its wholesale acquisition price has remained unchanged at $1,850 per dose—$150 less than Lucentis (at $2,000). ¶¶ 23–24.

The Complaint alleges that a cheaper treatment called Avastin (bevacizumab), also manufactured by Genentech, can treat wet AMD. ¶¶ 24, 26. But Avastin is a cancer drug. It is not approved to treat wet AMD, or any other retinal condition, and the FDA prohibits marketing it for that purpose, 21 U.S.C. § 331(a); *see* Ex. 9 at 1. Further, before being used to treat wet AMD, Avastin must be compounded and repackaged. DOJ Compl. ¶ 30. That process, as the FDA has cautioned, "could affect the safety and effectiveness of the product," and, if done improperly, "can cause serious adverse events." Ex. 10 at 4.

III. Regeneron's Charitable Donations to CDF

Medicare patients, including those covered by Medicare Advantage policies such as

Humana's, typically must pay copay, co-insurance, or deductible amounts ("copays"). These payments can impose a significant financial obstacle for certain patients. ¶¶ 30, 49; Ex. 12 at 1. Independent charities like CDF assist low- and middle-income patients by covering copays through contributions from manufacturers and others. ¶¶ 67–69; Ex. 13 at 1, 4–5. Federal law expressly authorizes manufacturers to fund such charitable support for patient copays. A 2005 bulletin issued by the United States Department of Health and Human Services ("HHS") Office of Inspector General ("OIG"), ¶¶ 70–77, emphasized that HHS

> is mindful of the importance of ensuring that financially needy beneficiaries who enroll in [Medicare] Part D receive medically necessary drugs, and ***OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries***, as long as the assistance is provided in a manner that does not run afoul of the Federal anti-kickback statute or other laws. . . . ***[C]ost-sharing subsidies provided by bona fide, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions***.

Ex. 13 at 1–2 (emphasis added).

Humana policies likewise permit policyholders to obtain copay assistance from charities such as CDF. The sample Humana "Evidence of Coverage" annexed to the Complaint encourages policyholders to seek assistance from "programs to help people with limited resources pay for their drugs." Ex. 2 at 111; *id*. at 124. And it assures policyholders that "payments are also included if they are made on your behalf by **certain other individuals or organizations**," including "by most charities," and such charitable payments count toward the out-of-pocket costs in the same manner as payments made by the patient. *Id*. at 122 (emphasis in original); 114 (same).

Beginning in 2011, when EYLEA first received FDA approval, Regeneron made contributions to CDF to assist AMD patients with copays. ¶¶ 22, 88. Humana does not, and cannot, allege that Regeneron's donations to CDF were earmarked for EYLEA patients. As shown in the exhibits annexed to the Complaint, and as DOJ alleges, contributions to CDF's AMD fund were pooled by CDF and allocated first-come, first-served to eligible AMD patients

treated with Lucentis as well as EYLEA (or potentially any other drug approved by the FDA). *See* Ex. 3 at 59; Ex. 4 at 1. Neither Humana nor DOJ alleges that Regeneron played any role in determining which CDF patients received assistance or in what amounts.

CDF's support for AMD patients receiving EYLEA, and Regeneron's assistance to patients to obtain such support, were no secret. On the contrary, the Complaint alleges that Regeneron, through a consulting firm, the Lash Group, "promoted the fact that 'charitable' funding was available" through "a program that it called EYLEA4U," ¶¶ 132–33, and that the availability of such funding was "widely known among prescribing physicians." ¶ 144. Indeed, Humana permitted its insureds to receive such funding. *See* Ex. 2 at 114, 122.

Humana claims that Regeneron's CDF contributions between 2013 and January 2014 violated the False Claims Act and the Federal Anti-Kickback statute ("AKS"), 42 U.S.C. § 1320a-7b. ¶ 10, because during that period of less than two years, CDF allegedly gave estimates to Regeneron employees of the monetary support it anticipated providing to EYLEA patients. Humana alleges that this information permitted Regeneron to tailor its donations for those years to offset the anticipated copays of EYLEA patients. ¶ 2. Humana claims that it is entitled to damages in the amount of the "payments it made where Regeneron, either directly or through CDF or another third-party conduit, paid Humana members' cost-sharing obligations." ¶ 183, for the entire period 2013 through the present.

While Regeneron's alleged conduct prior to 2014 is entirely appropriate, as explained more fully herein, the Complaint does not even allege facts supporting any purported misconduct later than January 2014—more than six years before Humana commenced this action. ¶¶ 109–112. That is no surprise: the DOJ Complaint, on which Humana's Complaint almost entirely relies, similarly alleges no purported wrongdoing after January 2014. *See* Ex. 5 at ¶ 70.

Humana's allegation that the "scheme described above continued in much the same way after 2014 and, on information and belief, through the present," ¶ 167, is unsupported by particularized facts. That EYLEA's price has not decreased since 2014 while sales volume and profits increased, ¶¶ 170–172, does not support any inference of misconduct. Nor do Humana's allegations that EYLEA patients have continued to receive copay assistance and that Regeneron has donated to CDF. ¶ 168. Such conduct is entirely lawful and authorized by documents incorporated in the Complaint, including the Humana plan documents and OIG bulletins discussed above. ¶¶ 67–70; Ex. 2.

IV. The DOJ Investigation and Lawsuit

In February 2017, Regeneron publicly disclosed that DOJ had commenced an investigation focusing on its "support of 501(c)(3) organizations that provide financial assistance to patients [and its] provision of financial assistance to patients with respect to products sold or developed by [Regeneron] (including EYLEA. . .)." Ex. 14 at 58.

On June 24, 2020, DOJ filed suit against Regeneron in the U.S. District Court for the District of Massachusetts. The DOJ Complaint asserts claims under the False Claims Act, 31 U.S.C. § 3729, and for unjust enrichment on the ground that Regeneron allegedly violated the AKS in donating to CDF after receiving projections of patient need from CDF. DOJ Compl. ¶¶ 102–12. Regeneron moved to dismiss on grounds not relevant to the present motion, and on December 4, 2020, the court denied Regeneron's motion to dismiss. The parties are in active discovery. The scheduling order in that case provides for completion of fact discovery by January 21, 2022 (less than four months from now), completion of expert discovery by June 14, 2022, and submission of summary judgment motions by June 30, 2022. Ex. 15.

V. Humana's Complaint

On July 22, 2021—nearly four and a half years after Regeneron first publicly disclosed

the DOJ investigation—Humana filed this lawsuit. The Complaint tracks, largely verbatim, a complaint filed in December 2020 by another insurer (*UnitedHealthcare Insurance Co. et al.* v. *Regeneron Pharmaceuticals, Inc.* (the "UHC Action")). The allegations in both complaints track those in the DOJ Complaint. Humana does not (and cannot) plead a claim under the False Claims Act, as DOJ does. Instead, it purports to assert eight other causes of action: fraud and fraudulent concealment (Count I); tortious interference with contract (Count II); aiding and abetting tortious interference with contract (Count III); civil RICO and conspiracy to violate RICO (Counts IV and V); unjust enrichment (Count VI); violation of state consumer protection statutes (Count VII); and violation of state insurance fraud statutes (Count VIII).

VI. Humana Was on Inquiry Notice for Years Before Commencing This Action

Humana has been on notice for years of the allegations on which its claims are based. These include: (i) that Regeneron contributed to copay foundations that assist patients with the costs of EYLEA, including Medicare patients; (ii) that CDF was the focus of investigations concerning allegedly improper relationships with pharmaceutical manufacturer donors; and (iii) that numerous other pharmaceutical manufacturers were the subjects of DOJ investigations concerning allegedly improper donations to copay foundations, including CDF. Humana has been on notice since Regeneron's disclosure in February 2017 that DOJ was investigating Regeneron's contributions to copay foundations that assisted EYLEA patients.

In particular, beginning in 2011, Regeneron repeatedly disclosed that it contributed to charitable organizations that assisted EYLEA users, including Medicare recipients. During an investor call about EYLEA on November 18, 2011, for example, Regeneron stated that "[g]overnment insured patients will be referred to a third-party charitable foundation for copay assistance. As part of our corporate . . . commitment to the underserved patient population, Regeneron provides unrestricted grants to some of these charitable organizations." Ex. 16 at 8.

Regeneron disclosed these contributions in subsequent investor calls and public filings. *See, e.g.*, Ex. 17 at 38 (discussing Regeneron's "contributions to a not-for-profit organization that assists patients with chronic disease conditions"). Humana does not claim to have been unaware that CDF supported EYLEA patients. ¶¶ 138, 141.

Starting in late 2013, allegations of misconduct involving contributions to CDF by pharmaceutical manufacturers, as well as the enhanced government scrutiny and enforcement that followed, were widely reported. In October 2013, for example, *Barron's* reported on questions about CDF's compliance with HHS guidance in connection with assistance to patients using a drug manufactured by one of its contributors. It noted:

> The OIG's September 2006 advisory letter [to CDF] said the agency wouldn't challenge the CDF's program, as long as drug-company donors didn't influence the charity's choice of targeted diseases and a drug maker's contributions weren't earmarked for its own products. How well the CDF has abided by those commitments is a fair question . . . .

Ex. 18 at 2–3; *see also* Exs. 19–20. Two months later, in December 2013, the *New York Times* reported that CDF had revamped its entire Board in light of alleged misconduct relating to Questcor. Ex. 21 at 1; *see also* Ex. 22. In 2015, the *LA Times* reported on the "too cozy" relationship between Questcor and CDF and the "suspect nature" of charity-funded patient assistance programs in general. Ex. 23 at 3. Multiple reports in 2016 publicized broad government investigations into contributions by pharmaceutical companies to charitable copay assistance organizations. Exs. 24–29. As early as May 2017, press reports disclosed that the Internal Revenue Service was investigating allegedly improper donations to CDF by pharmaceutical companies that potentially threatened its tax-exempt status. Exs. 30–32.

Further, since at least 2016, DOJ has been engaged in widely publicized, industry-wide investigations of "the relationships between pharmaceutical companies and purportedly independent charities," and has entered into public settlements with other pharmaceutical

companies relating to donations to CDF and other copay assistance charities. ¶¶ 173–75. Humana alleges that these investigations were based upon schemes "like the one alleged in this Complaint." ¶ 173; *see also* Ex. 33 at 2, 4.

PLEADING STANDARDS

Humana's claims for fraud, fraudulent concealment, insurance fraud, and RICO are subject to the heightened pleading standard that requires plaintiffs to "state with particularity the circumstances constituting fraud or mistake," Fed. R. Civ. P. 9(b), and to allege facts that give rise to a "strong inference of fraudulent intent." *First Cap. Asset Mgmt., Inc.* v. *Satinwood, Inc.*, 385 F.3d 159, 178–79 (2d Cir. 2004); *Hodges* v. *Glenholme Sch.*, 713 F. App'x 49, 51 (2d Cir. 2017) (holding same for fraudulent concealment claim). Courts have emphasized that RICO claims "should be 'flush[ed] out' at early stages of the litigation" because such claims "not only have a stigmatizing effect on those named as defendants, but carry also the possibility of treble damages." *Cedar Swamp Holdings*, 487 F. Supp. 2d at 449.

Humana's remaining claims are subject to the "plausibility" standard established by *Bell Atlantic Corp* v. *Twombly*, 550 U.S. 544 (2007), and *Ashcroft* v. *Iqbal*, 556 U.S. 662 (2009). That standard requires the plaintiffs to plead "enough facts to state a claim to relief that is plausible on its face," *Twombly*, 550 U.S. at 570, and to provide sufficient "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

On a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the Court may consider the facts alleged in the Complaint, as well as "documents attached to the complaint as exhibits, and any documents incorporated by reference." *McCarthy* v. *Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007). The Court also may consider documents "integral to plaintiffs' claim." *Cortec Indus., Inc.* v. *Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991). Here, the DOJ Complaint, upon

which Humana repeatedly relies as the source for its claims, is such an integral document. *See Gerard* v. *Traffic Safety, LLC*, 2012 WL 2866255, at *3 n.1 (S.D.N.Y. July 2, 2012) (Briccetti, J.) (a separate complaint was integral to the complaint on a motion to dismiss because plaintiff relied on it in framing its complaint). The Court may also consider publicly available information, including press releases, earnings reports, news reports, and court filings, in assessing whether the plaintiff was on notice of its claims for statute of limitations purposes. *See, e.g.*, *Staehr* v. *Hartford Fin. Servs. Corp.*, 547 F.3d 406, 425 (2d Cir. 2008).

ARGUMENT

I. All of Humana's Claims Are Time-Barred.

Humana's claims are untimely. The relevant limitations periods are six years or less, and the Complaint pleads no misconduct after early 2014, more than seven years before this case was commenced. Humana's claims are also barred under limitations periods based upon inquiry notice, and they are not saved by the "continuing wrong" and "discovery rule" doctrines.

A. Humana's Claims in Counts II, III, VI, and VII are Untimely Because They Accrued More than Six Years Before This Action Was Commenced.

Humana's claims for tortious interference, aiding and abetting tortious interference, unjust enrichment, and under the consumer protection statutes of New York and certain other states (Counts II, III, VI, and VII) are time-barred. Each claim has a limitations period of six years or less after the claim accrues.[1] The Complaint alleges no facts showing misconduct later than January 2014—over seven years before this action was commenced in July 2021, and accordingly, each of these claims is time-barred. Humana's conclusory and unsupported allegations that misconduct "commenced in mid-2012 and continued for years thereafter to the present," ¶ 250, fail the *Twombly* and *Iqbal* "plausibility" standard, much less the more stringent

[1] *See* Appendix A (setting forth limitations periods for Humana's claims).

Rule 9(b) standard.

As the Court held in *Atl. Int'l Movers, LLC* v. *Ocean World Lines*, 914 F. Supp. 2d 267 (E.D.N.Y. 2012), an allegation that the defendants' tortious conduct "continued into at least on or around 2010"—an allegation almost identical to that here—was "conclusory" and did not save the time-barred claim. *Id*. at 279. Similarly, in *World Wrestling Ent., Inc.* v. *Jakks Pac., Inc.*[2], the Second Circuit affirmed the district court's holding that plaintiff's factual allegations of lawful conduct—for "paying (or receiving) royalties pursuant to a contract"—did not support an inference of misconduct that extended the pattern of racketeering activity for statute of limitations purposes.

B. Humana's Remaining Claims Are Time-Barred by Inquiry Notice.

Plaintiff's remaining claims, which are subject to the even shorter limitations period of no more than four years from the time that Humana knew or should have known of its claims, are likewise time-barred. A mountain of publicly available information—including broadly reported, industry-wide investigations into matters that Humana concedes are "like the one alleged in this Complaint," ¶ 173—put Humana on notice of its claims at least as early as February 2017, more than four years before it commenced this action. *See* N.Y. C.P.L.R. 213(8) (fraud limitations period is the "greater of six years from the date the cause of action accrued or two years from the time the plaintiff . . . discovered the fraud, or could with reasonable diligence have discovered it"); *Koch* v. *Christie's Int'l PLC*, 699 F.3d 141, 148 (2d Cir. 2012) (civil RICO limitations period is four years from when plaintiff "has 'inquiry notice' of his injury, namely when he discovers or reasonably should have discovered the RICO injury").[3] Humana's failure to

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[2] 530 F. Supp. 2d 486, 510–12 (S.D.N.Y. 2007) *aff'd*, 328 F. App'x 695 (2d Cir. 2009).

[3] *See also* Appendix A.

exercise diligence in asserting its purported claims for more than four years, or five years for two of the civil insurance fraud states in Count VIII, bars it from pursuing those claims now.

The inquiry notice standard requires only notice, not actual knowledge. For Humana's fraud claim, whether a plaintiff could "with reasonable diligence" have discovered the alleged fraud "turns on whether the plaintiff was possessed of knowledge of facts from which [the fraud] could be reasonably inferred." *Sargiss* v. *Magarelli*, 12 N.Y.3d 527, 532 (2009). This determination is based on a "a totality-of-the-circumstances analysis" of the "objective facts and circumstances, taken as a whole." *Staehr*, 547 F.3d at 427 (internal citations omitted). Inquiry notice for RICO claims is substantively the same as inquiry notice for fraud in New York. *Koch*, 699 F.3d at 156*; see also* Appendix B (setting forth the grounds for dismissal for the state consumer protection laws alleged in Count VII). Whether a plaintiff was on inquiry notice "need not be left to a finder of fact," and can be resolved on a motion to dismiss. *In re Merrill Lynch Ltd. P'ships Litig*., 154 F.3d 56, 60 (2d Cir. 1998).[4]

The inquiry notice standard holds "plaintiffs to a high standard." *Koch*, 699 F.3d at 150. It turns on whether a person of "ordinary intelligence would consider it 'probable' that fraud had occurred" based on "storm warnings" of fraud. *Koch*, 699 F.3d at 151 (quotation omitted); *see also Sonterra Cap. Master Fund, Ltd.* v. *Barclays Bank PLC*, 366 F. Supp. 3d 516, 525 (S.D.N.Y. 2018). Once there are "sufficient 'storm warnings' to trigger the duty to inquire, and the duty arises, if a plaintiff does not inquire within the limitations period, the claim will be time-barred." *Koch*, 699 F.3d at 153, 156 (applying to RICO and New York common law fraud). The

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[4] *See also Koch* v. *Christie's Int'l PLC*, 699 F.3d 141 (2d Cir. 2012); *Aozora Bank, Ltd.* v. *UBS AG*, 40 N.Y.S.3d 406 (1st Dep't 2016); *TMG–II* v. *Price Waterhouse & Co*., 572 N.Y.S.2d 6 (1st Dep't 1991); *421-A Tenants Ass'n Inc.* v. *125 Court St. LLC*, 2017 WL 6612933 (E.D.N.Y. Nov. 2, 2017); *Certain Underwriters at Lloyd's* v. *Milberg LLP*, 2009 WL 3241489 (S.D.N.Y. Sept. 30, 2009).

Complaint does not allege that Humana, one of the largest health insurers, was unaware of industry investigations into copay foundations. Nor could it plausibly do so, given the wide range of information available to it for years before it commenced this action—including information publicly disclosed by Regeneron itself. Humana's utter lack of diligence in asserting its claims does not come close to meeting the "high standard" for inquiry notice demanded of plaintiffs.

Courts have held that similar public disclosures of investigations and press reports about potential misconduct may give rise to inquiry notice. In *Aozora Bank, Ltd.* v. *UBS AG*, 40 N.Y.S.3d 406, 407 (1st Dep't 2016), for example, the court dismissed the complaint on the ground that the plaintiff was put on inquiry notice by news articles disclosing the participation of similar institutions in misconduct related to the allegations in the complaint; the disclosure of an SEC investigation; and the filing of similar lawsuits against certain of the defendants. Applying the same principles, courts have held that plaintiffs were placed on inquiry notice by public disclosure of an IRS investigation and press reports about the company;[5] by public disclosure of a government investigation;[6] by patent records, announcement of a patent lawsuit, and newspaper articles;[7] and by prior lawsuits involving similar claims.[8]

Humana's RICO and fraud claims (and five of the state law consumer protection claims listed in Appendix A) are untimely under these standards. As described above, publicly available information about alleged improper contributions by pharmaceutical manufacturers to CDF and other copay assistance charities placed Humana on notice of potential claims more than four

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5 *TMG–II* v. *Price Waterhouse & Co.*, 572 N.Y.S.2d 6, 7 (1st Dep't 1991).

6 *Certain Underwriters at Lloyd's* v. *Milberg LLP*, 2009 WL 3241489, at *8–9 (S.D.N.Y. Sept. 30, 2009).

7 *Doukas* v. *Ballard*, 972 N.Y.S.2d 143, 143 (N.Y. Sup. Ct. 2013).

8 *421-A Tenants Ass'n Inc.* v. *125 Court St. LLC*, 2017 WL 6612933, at *6 (E.D.N.Y. Nov. 2, 2017).

years before this action was commenced. *See* pp. 10–12. Humana's fraud claim—with its shorter two-year limitations period from inquiry notice—is further barred by public disclosures more than two years before this action was commenced, including Regeneron's disclosure of the DOJ investigation in February 2017. *Id.*; Ex. 14 at 58. Humana does not allege that it made any inquiry about these public disclosures. As the courts held in *Aozora* and the other cases cited above, a plaintiff—particularly a highly sophisticated business conglomerate like Humana—may not hide its head in the sand in the face of information suggesting that it may have a claim. Humana had an affirmative obligation to inquire, and its failure to do so is fatal here.

For these reasons, Humana's claims are time-barred and should be dismissed.

C. Equitable Tolling, the "Continuing Wrong" Doctrine, and the Separate Accrual Rule Do Not Save Humana's Claims.

Humana attempts to salvage its time-barred claims by invoking a variety of limitations period-related doctrines. ¶¶ 185–86. The continuing wrong doctrine provides that "a series of continuing wrongs may toll the period of limitations until the commission of the last wrongful act." *Bryant* v. *Broad. Music Inc.*, 721 F. App'x 78, 80 (2d Cir. 2018). The "continuing wrong" doctrine does not apply because the Complaint does not allege with the required specificity any misconduct later than January 2014.

The separate accrual rule provides that a new cause of action arises "each time plaintiff discovers or should have discovered an injury caused by defendant's violation of [RICO] § 1962." *Bankers Tr. Co.* v. *Rhoades*, 859 F.2d 1096, 1105 (2d Cir. 1988). The "separate accrual" rule is likewise inapposite, as the Complaint does not allege non-time barred conduct by Regeneron to conceal the alleged fraud; to the contrary, Humana was repeatedly placed on notice of its purported claims and failed to conduct any inquiry or assert those claims.

Humana's lack of inquiry similarly bars application of the "discovery rule"—which

allows the limitations period to run from when the plaintiff "first knows or with due diligence should know facts that will form the basis for an action," *Merck & Co., Inc.* v. *Reynolds*, 559 U.S. 633, 646 (2010)—and the doctrine of equitable tolling. Mere allegations that the defendant did not affirmatively disclose the alleged wrongdoing—which is all that is alleged here—do not support equitable tolling. *See Koch* v. *Christie's Int'l PLC*, 699 F.3d 141 (2d Cir. 2012). Regeneron was not obligated "to make a public confession," or "to alert people who may have claims against it." *Zumpano*, 6 N.Y.3d at 675. And the Complaint alleges no facts showing efforts by Regeneron to prevent Humana from asserting its claims "above and beyond the wrongdoing upon which [Humana's] claim is founded." *S.E.C.* v. *Wyly*, 788 F. Supp. 2d 92, 104 n.78 (S.D.N.Y. 2011). As a sophisticated health insurer, Humana has not alleged facts showing it was reasonably diligent in investigating its claims. As the Second Circuit has emphasized, "[r]easonable diligence is a prerequisite to the applicability of equitable tolling" under federal and New York law. *Koch*, 699 F.3d at 157; *Abbas* v. *Dixon*, 480 F.3d 636, 642 (2d Cir. 2007).

II. Humana's RICO Claims Should Be Dismissed.

To plead a claim for violation of civil RICO under 18 U.S.C. § 1962(c), Humana must allege with particularity "(1) that the defendant (2) through the commission of two or more acts (3) constituting a 'pattern' (4) of 'racketeering activity' (5) directly or indirectly invests in, or maintains an interest in, or participates in (6) an 'enterprise' (7) the activities of which affect interstate or foreign commerce" and that its alleged injuries were "by reason of" the violation. *Moss* v. *Morgan Stanley, Inc.*, 719 F.2d 5, 17 (2d Cir. 1983). Humana's RICO claims (Counts IV and V) should be dismissed because they fail adequately to allege (i) a pattern of racketeering, (ii) a RICO enterprise, or (iii) proximate cause. Without an underlying violation, Humana's claim for alleged RICO conspiracy (Count V) also should be dismissed. As the court emphasized in *Cedar Swamp Holdings*, RICO claims should be "'flush[ed] out' at early stages of the

litigation." 487 F. Supp. 2d at 449. The Court should do so here.

A. The Complaint Does Not Plead a Pattern of Racketeering.

Humana does not plead a "pattern of racketeering," 18 U.S.C. § 1962(c), which requires Humana to adequately plead a threat of continuous criminal activity through either "a closed period of repeated conduct, or [] past conduct that by its nature projects into the future with a threat of repetition." *Horowitz* v. *QFA Royalties*, 2012 WL 5995237, at *6 (S.D.N.Y. Sept. 27, 2012) (Briccetti, J.) (citing *H.J. Inc.* v. *Nw. Bell Tel. Co*., 492 U.S. 229, 240 (1989)). Here, the facts alleged do not show either type of pattern.

No closed-ended continuity because the alleged racketeering activity occurred for less than two years. To plead closed-ended continuity, Humana must allege a series of related predicate acts that extend "over a substantial period of time." *Spool* v. *World Child Int'l Adoption Agency*, 520 F.3d 178, 184 (2d Cir. 2008). To assess the adequacy of the pleading, courts assess the "length of time over which the alleged predicate acts took place, the number and variety of acts, the number of participants, the number of victims, and the presence of separate schemes." *GICC Cap. Corp.* v. *Tech. Fin. Grp., Inc.*, 67 F.3d 463, 467 (2d Cir. 1995).

The Second Circuit imposes a bright-line rule that the requisite "substantial period of time" must be "at least two years." *AmBase Corp.* v. *111 W. 57th Sponsor LLC*, 785 F. App'x 886, 888 (2d Cir. 2019). The Second Circuit "has never held a period of racketeering activity lasting less than two years to be substantial enough to qualify as closed-ended continuity." *Kalimantano GmbH* v. *Motion in Time, Inc.*, 939 F. Supp. 2d 392, 412 (S.D.N.Y. 2013). Thus, in *Horowitz*, this Court held that the complaint failed to allege closed-ended continuity where the alleged predicate acts spanned 21 months. 2012 WL 5995237, at *6 (Briccetti, J.). As noted above, p. 8, the Complaint alleges wrongdoing over approximately 13 months (2013 through January 2014), ¶¶ 2, 127–129, a period insufficient to show closed-ended continuity. The only

post-2014 allegations are either irrelevant to wrongdoing (*e.g.*, regarding EYLEA's price, sales volume, or profits), or concern practices expressly authorized by documents referred to in, or annexed to, the Complaint (*e.g.*, that EYLEA patients continued to receive copay assistance and that Regeneron continued to make lawful contributions to CDF). ¶¶ 168–172.

Other factors weigh against closed-ended continuity. While Regeneron's conduct in providing funding to CDF was appropriate in all respects, the scheme alleged in the Complaint was "essentially a single, relatively simple fraudulent scheme with a single purpose" and "there was no variety in the underlying transactions." *Gross* v. *Waywell*, 628 F. Supp. 2d 475, 496 (S.D.N.Y. 2009). Such "allegations [that] stem from a single, allegedly fraudulent act . . . cannot form the basis for a civil RICO claim." *Liang* v. *Home Reno Concepts, LLC*, 803 F. App'x 444, 448 (2d Cir. 2020); *see also Morris* v. *Zimmer*, 2011 WL 5533339, at *11 (S.D.N.Y. Nov. 10, 2011) (Briccetti, J.) (no closed-ended continuity where alleged misrepresentations were "all subparts of the singular act, and not a pattern of separate acts with an underlying purpose") (internal quotation marks omitted).

The plain language of Humana's Complaint shows that the purported fraud had only a *single* alleged purpose—"to fraudulently induce payors, including Humana, to pay claims for EYLEA," ¶ 247—that was effected by the singular mechanism of allegedly channeling improper donations to CDF. Humana's attempts at "artificially fragmenting a singular act into multiple acts simply to invoke RICO," *Schlaifer Nance & Co.* v. *Est. of Warhol*, 119 F.3d 91, 98 (2d Cir. 1997)—by "coordinating the unlawful payments," disseminating false and misleading information, "causing physicians to transmit false claims," ¶ 248—is the type of gerrymandering routinely rejected by courts. *Schlaifer*, 119 F.3d at 98; *Marcoux*, 2006 WL 842888, at *12.

Humana does not sufficiently plead open-ended continuity. Nor does Humana plead an

open-ended pattern, which requires either that the "predicate acts were the regular way of operating that business, or that the nature of the predicate acts themselves implies a threat of continued criminal activity." *Spool*, 520 F.3d at 185. In particular, allegations of "inherently terminable" conduct cannot show open-ended continuity. *Id.* at 186; *Cofacredit, S.A.* v. *Windsor Plumbing Supply Co.*, 187 F.3d 229, 244 (2d Cir. 1999).

Here, the alleged conduct at issue—Regeneron's alleged use of CDF's projections of its assistance to EYLEA patients in 2013 and 2014 to plan the amount of Regeneron's charitable contributions to CDF—is "inherently terminable," because it pertains to a discrete series of funding decisions made on a quarterly basis. ¶¶ 90–112. Humana's bare legal conclusions to the contrary, ¶ 249, are not supported by particularized facts.

The absence of open-ended continuity is particularly clear since the last alleged instance of misconduct occurred nearly seven and a half years before this action was commenced. *Ramiro Aviles* v. *S & P Glob., Inc.*, 380 F. Supp. 3d 221, 268–69 (S.D.N.Y. 2019) (no open-ended continuity where there were no predicate acts for years before complaint was filed). Humana's conclusory claim of continuing misconduct does not overcome this deficiency. *Purchase Real Estate Grp. Inc.* v. *Jones*, 2010 WL 3377504, at *11 (S.D.N.Y. Aug. 24, 2010) (no open-ended continuity despite "Plaintiffs' conclusory assertions" of continuing misconduct because the complaint provided no "basis from which th[e] Court c[ould] conclude that continuation or repetition . . . was likely at the time the Complaint was filed"); *Aronov* v. *Mersini*, 2015 WL 1780164, at *7 (S.D.N.Y. Apr. 20, 2015) (failure to "allege that any predicate acts have occurred since" a date certain "suggests that the alleged scheme has come to a close.").

B. The Complaint Does Not Plead a RICO "Enterprise."

To plead a RICO enterprise, a plaintiff must show that the defendant was part of "a group of persons associated together for a common purpose of engaging in a course of conduct."

United States v. *Turkette*, 452 U.S. 576, 583 (1981). The alleged enterprise must be "separate and distinct from the alleged predicate racketeering acts themselves." *First Cap. Asset Mgmt.*, 385 F.3d at 174. The complaint must show the existence of an enterprise "by evidence of an ongoing organization, formal or informal, and by evidence that the various associates function[ed] as a continuing unit," *Turkette*, 452 U.S. at 583, and "solid information regarding the 'hierarchy, organization, and activities'" of the alleged enterprise. *First Cap. Asset Mgmt.*, 385 F.3d at 175 (quoting *United States* v. *Coonan*, 938 F.2d 1553, 1560–61 (2d Cir. 1991)). Humana's allegations that Regeneron, CDF, and the Lash Group constituted a RICO enterprise, ¶ 237, fall short in at least three ways.

First, the Complaint does not show an "enterprise" distinct from the alleged predicate acts. Rather, it defines the alleged enterprise as no more than its members working together "to effectuate a pattern of racketeering activity." ¶ 237. It alleges, for example, that "Regeneron established the Enterprise to inflate the price, and increase the sales, of EYLEA," ¶ 238, that CDF was "enlisted" to "launder illegal payments targeted to eliminate the cost-sharing obligations of Eylea patients," and that Lash Group was "enlisted" to "advertise the availability of the resulting funds, to facilitate CDF funding for Eylea patients, and to monitor and facilitate reimbursements for Eylea by payors like [Humana]." *Id.* Humana further alleges that Lash Group and CDF both "profited from the Enterprise's illicit activities" through administrative fees. *Id.* at ¶ 240.

These allegations underscore how the sole conduct connecting the alleged Enterprise members is the alleged racketeering acts themselves. That the "relationships between Regeneron, CDF, and the Lash Group extended beyond the unlawful predicate acts at issue in this case" and that the "illegal scheme at issue in this litigation was and is distinct from any legitimate business

activities undertaken by Regeneron, CDF, and the Lash Group" are bare legal conclusions untethered to particularized facts. ¶ 242. Nor do the vague references to "Regeneron's relationship with the CDF predat[ing] the scheme" and "other, lawful aspects of the EYLEA4U program" supply the missing factual allegations. *Id.*

The decision in *Cruz* v. *FXDirectDealer*, 855 F. Supp. 2d 89 (S.D.N.Y. 2012), *aff'd in relevant part, vacated in part, remanded*, 720 F.3d 115 (2d Cir. 2013), is illustrative. There, an investor alleged that the defendant trading service violated RICO in connection with the use of trading platforms that fraudulently manipulated the trading process. *Id.* at 95. Plaintiffs alleged that defendants were part of an enterprise consisting of a "group of persons associated together for the common purpose of employing the multiple deceptive, abusive and fraudulent acts alleged in the Amended Complaint." *Id.* (internal quotation marks omitted). The court dismissed the plaintiffs' RICO claim on the ground that these allegations, rather than showing a distinct enterprise, merely alleged that the members of the enterprise "came together strictly for the purpose of facilitating [the] allegedly deceptive trading practices." *Id.* at 99 (internal quotation marks omitted); *see also Kottler* v. *Deutsche Bank AG*, 607 F. Supp. 2d 447, 458–59 (S.D.N.Y. 2009) (no distinct enterprise where complaint alleged that the defendants associated "strictly for the purpose of creating [the] allegedly fraudulent tax shelters"). Plaintiff's RICO claims are likewise fatally deficient because they fail to allege a distinct enterprise.

Second, the Complaint does not show an organization that "functioned as a unit" or anything else beyond an ongoing relationship between independent entities, as "individuals or entities whose activities sometimes intersect do not form an enterprise." *In re: Gen. Motors LLC Ignition Switch Litig*., 2016 WL 3920353, at *12 (S.D.N.Y. July 15, 2016); *see also Bonadio* v. *PHH Mortg. Corp.*, 2014 WL 522784 (S.D.N.Y. Jan. 31, 2014) (Briccetti, J.).

Third, the enterprise allegations in the Complaint are bare legal conclusions rather than facts. The Complaint alleges, for example, that "Regeneron, CDF, and the Lash Group entered into an association-in-fact enterprise . . . [as] an ongoing organization that functioned as a continuing unit"; that the "Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity"; and that "Regeneron, CDF and the Lash Group are each 'persons' distinct from the Enterprise." ¶ 237. Such formulaic recitations are insufficient. *See, e.g.*, *Hoatson* v. *New York Archdiocese*, 2007 WL 431098, at *3 (S.D.N.Y. Feb. 8, 2007), *aff'd*, 280 F. App'x 88 (2d Cir. 2008) (dismissing complaint where other than "wholly conclusory allegations, Plaintiff [did] not allege any facts that the defendants functioned 'as a continuing unit,' or were 'an entity separate and apart' from their alleged illegal activities").

C. The Complaint Does Not Plead Proximate Cause.

Humana's RICO claims should also be dismissed because the Complaint fails to plead a "direct" causal connection between Regeneron's conduct and Humana's alleged injuries. *See Anza* v. *Ideal Steel Supply Corp.*, 547 U.S. 451, 461 (2006). RICO requires "a more stringent showing of proximate cause than would be required at common law," *Lerner* v. *Fleet Bank, N.A.*, 459 F.3d 273, 285 n.5 (2d Cir. 2006) (citations omitted), and requires the Court to avoid "intricate, uncertain inquiries [about causation] from overrunning RICO litigation," *Empire Merchants, LLC* v. *Reliable Churchill LLP*, 902 F.3d 132, 143 (2d Cir. 2018). In particular, "it is usually easier for interveners to break the chain of causation in RICO than it is at common law." *Lerner*, 459 F.3d at 285 n.5 (citation omitted). Proximate cause is not shown if "substantial intervening factors attenuate the causal connection between the defendant's conduct and the plaintiff's injury." *Doe* v. *Trump Corp.*, 385 F. Supp. 3d 265, 277 (S.D.N.Y. 2019).

The Complaint fails the "stringent" standard. Humana claims to have been injured through "payments made for EYLEA that Humana otherwise would not have made." ¶ 119. But

this summary allegation short-circuits a lengthy, complicated, and highly individualized causal chain reliant on the decisions of multiple independent actors: (i) the physician must exercise independent medical judgment in diagnosing a patient with wet AMD; (ii) the physician must exercise independent medical judgment to determine whether to prescribe and administer a wet AMD drug to that patient; (iii) the physician must exercise independent medical judgment to prescribe EYLEA for that patient rather than its on-label alternative Lucentis, or the off-label and unapproved alternative Avastin; (iv) the physician must purchase EYLEA from a distributor; (v) if EYLEA is prescribed, the patient must apply to CDF for copay assistance (as opposed to any other charitable foundations); (vi) CDF must have funding available at that time; (vii) CDF must evaluate and approve the patient's application; (viii) the physician must submit a claim to CDF to cover the copay instead of receiving it from the patient; and (ix) after treating the patient, the physician must seek, and be approved for, reimbursement from Humana. ¶ 87.

Each link in this lengthy causal chain rests on decisions by independent third parties—including physicians, patients, and CDF—that are wholly unrelated to any alleged conduct by Regeneron. Humana's theory of damages rests on assumptions about how these independent entities would have acted that is unsupported by any facts alleged in the Complaint. Such speculation does not satisfy Humana's obligation to plead proximate cause, particularly the 'stringent' pleading requirements applicable to its RICO claims. *Lerner*, 459 F.3d at 285 n.5.

Humana's claims based on this attenuated and speculative causal chain are further undermined by the fact that its reimbursement costs would be *greater* if physicians instead chose to prescribe EYLEA's main on-label—and more expensive—competitor, Lucentis. ¶¶ 23–24. While the Complaint speculates that health care professionals might have prescribed off-label

Avastin, it does not allege that they prefer Avastin to Lucentis as an alternative to EYLEA.[9] Nor does the Complaint show that Humana would have been entitled to reject otherwise valid claims for EYLEA because of alleged CDF-Regeneron interactions.

As the Second Circuit emphasized, "[t]he nature of prescriptions . . . means that this theory of causation is interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof." *UFCW Local 1776* v. *Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010) (summary judgment); *see also Sergeants Benevolent Ass'n Health & Welfare Fund* v. *Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305, 323 (E.D.N.Y. 2014) ("[T]he prescribing decisions of physicians are based on so many factors as to defy any efforts to categorically attribute them to a particular cause."), *aff'd*, 806 F.3d 71 (2d Cir. 2015). This attenuated causal chain prevents Humana, as a third-party payor, from establishing its RICO claim through Regeneron's allegedly "false and misleading information to physicians, patients, and the general public" ¶ 248(d). For example, multiple Circuit courts have held that "improper representations made to physicians do not support a RICO claim by Payors, several levels removed in the causal sequence." *Sidney Hillman Health Ctr. of Rochester* v. *Abbott Lab'ys*, 873 F.3d 574, 578 (7th Cir. 2017) (noting the Second Circuit holdings in *Sergeants Benevolent* and *UFCW Local* "that that there are so many layers, and so many independent decisions, between promotion and payment that the causal chain is too long to satisfy the Supreme Court's requirements," and agreeing with the Second Circuit and "two other circuits"). For all of these reasons, Humana's RICO claims should be dismissed.

[9] Plaintiff also cites the O'Neal Declaration (¶¶ 25, 149)—from an unrelated litigation concerning implementation of an improperly promulgated drug pricing rule—that has no bearing on physicians' decisions, in the absence of CDF copay assistance, to prescribe Avastin over EYLEA.

D. Humana's Claim for RICO Conspiracy Should Also Be Dismissed.

Because Humana has "failed to state a substantive RICO claim," its RICO "conspiracy claim [Count V] necessarily fails as well." *Vidurek* v. *Koskinen*, 2018 WL 3597644, *11 (S.D.N.Y. July 25, 2018) (Briccetti, J.) (citations omitted).

III. Humana's State Law Claims Should Be Dismissed.

A. The Complaint Fails to Plead a Claim for Fraud or Civil Insurance Fraud (Counts I and VIII)

Count I of the Complaint purports to assert a claim for "fraudulent concealment and fraud" ¶¶ 187–211. A fraud claim requires that Humana plead a false representation or omission of a material fact on which the plaintiff relied, while fraudulent concealment requires that the defendant concealed a material fact that the defendant had a duty to disclose. *See Pasternack* v. *Laboratory Corp. of Am. Holdings*, 27 N.Y.3d 817, 827 (2016).

The Complaint does not allege any misrepresentations by Regeneron upon which Humana relied. Instead, it alleges that Regeneron "concealed the nature of its financial relationship with and use of CDF," ¶ 8, but the Complaint does not allege any particularized facts showing that Humana relied on this alleged omission. Humana's failure to allege facts showing reliance is fatal to its fraud claim. *See Aetna Cas. & Sur. Co.* v. *Aniero Concrete Co.*, 404 F.3d 566, 583 (2d Cir. 2005) (dismissing claim because plaintiff "failed to set forth the precise circumstances in which it received [documents], and how those circumstances gave rise to a reasonable belief on plaintiff's part that they were comprehensive"). As in *Rapaport* v. *Strategic Fin. Sols., LLC*, Humana's only allegations of justifiable reliance are "conclusory and vague . . . [that] do not create an issue of fact." 140 N.Y.S.3d 508, 509 (1st Dep't 2021).

Humana's allegation that Regeneron "concealed the nature of its financial relationship with and use of CDF," ¶ 8, is insufficient for the additional reason that Humana does not allege

with particularity that Regeneron had a duty to disclose such information. Humana alleges that "Regeneron's superior knowledge" related to Humana's reimbursements for EYLEA created such a duty. ¶ 195. A plaintiff relying on alleged "superior knowledge" as the basis for a duty to disclose must satisfy New York's "special facts" doctrine, which imposes a duty only on "parties or potential parties to a transaction." *Fin. Guar. Ins. Co.* v. *Putnam Advisory Co., LLC*, 2020 WL 5518146, at *8 (S.D.N.Y. Sept. 14, 2020). The doctrine applies *only* where the allegedly undisclosed information is "peculiarly within the knowledge of [the defendant]" and could not have been discovered by the plaintiff "through the exercise of ordinary intelligence." *Jana L.* v. *W. 129th St. Realty Corp*., 802 N.Y.S.2d 132, 135 (1st Dep't 2005) (citation cleaned up).

The Complaint does not satisfy these standards. It does not allege that Humana could not have discovered the alleged misconduct through the "exercise of ordinary intelligence," *Jana L*., 802 N.Y.S.2d at 135. To the contrary, as shown above, pp. 15–17, once Humana was on inquiry notice, it had a duty to inquire but did not do so. The special facts doctrine cannot impute a duty to disclose where, as here, a plaintiff hides its head in the sand when put on notice of potential claims. *Id.* (since respondent "had, at the very least, a duty to inquire," it was "insufficient for [respondent] to simply make the conclusory statement that the information of an incident giving rise to liability could not have been obtained by it through the exercise of ordinary intelligence") (internal punctuation omitted). Humana's failure to allege that Regeneron had a duty to disclose its relationship with CDF is fatal to Humana's fraud claim.

Humana's reliance on the civil insurance fraud statutes of three states—Kentucky, Pennsylvania, and Tennessee—fares no better. Humana cannot adequately plead, as those statutes require, that Regeneron knowingly presented or caused to be presented information, false

or otherwise, that was material or part of a claim.[10] The Complaint does not and cannot allege that Regeneron made any claim to Humana or submitted any statement forming a part of an insured's claims. On the contrary, the only parties to transactions involving Humana's reimbursements for EYLEA are Humana, its insureds, and their medical providers. ¶ 213. Humana's attempt to fit a third-party manufacturer like Regeneron into civil insurance fraud statutes addressing the claims submission process stretches those statutes beyond recognition.

Nor does the Complaint adequately allege that any statement by Regeneron was material to Humana's decision to pay claims for EYLEA, particularly under the heightened pleading standard required for fraud. Instead, Humana relies wholly on the conclusory assertion that the "compliance certifications and other information submitted to Humana were material to Humana's decision to pay for Eylea claims." ¶ 288.

Barnes v. *Allstate Prop. & Cas. Ins. Co.* illustrates why the lack of adequately alleged materiality dooms Human's claim. 2013 WL 592207, at *3 (E.D. Pa. Feb. 15, 2013). There, the insurance company "summarily asserts that [the policyholder] misrepresented and concealed facts pertaining to various facets of his policy claim." *Id.* The Court dismissed the insurer's counter-claim because "it is difficult, on the basis of the threadbare allegations in the counterclaim, to assess whether the factual misstatements or omissions relate to matters that are 'material' to [the policyholder's] request for coverage." *Id.* Not only does materiality here similarly rest on "threadbare allegations," ¶ 288, but the defect is even *more glaring* than in *Barnes*, because Regeneron is not a policyholder, but a third-party pharmaceutical company that was not in privity with Humana and did not submit any claims to Humana.

[10] Ky. Rev. Stat. § 304.47-010; 18 Pa. Cons. Stat. Ann. § 4117; Tenn. Code Ann. § 56-53-101.

B. The Complaint Fails to State a Claim for Tortious Interference with Contract or Aiding and Abetting Tortious Interference (Counts II and III).

To plead a claim for tortious interference with contract or aiding and abetting such interference, a plaintiff must plead (i) an actual breach of the contract and (ii) the defendant's knowledge of the contract. *See Oddo Asset Mgmt*. v. *Barclays Bank PLC*, 19 N.Y.3d 584, 594 (2012). The Complaint fails on both counts.

The Complaint does not allege any breach of contract. Humana alleges that its Medicare Advantage and Medicare Prescription Drug plans "require Humana members to pay the cost-sharing obligations set forth in the plans when obtaining prescription drugs, including EYLEA," ¶ 214, and that "Regeneron's conduct and interference caused Humana members to breach their agreements with Humana when they failed to pay the cost-sharing obligations that Humana's benefit plans required." ¶ 245. But these allegations are contradicted by the "Evidence of Coverage" annexed to the Complaint that Humana alleges reflects the terms of its Medicare Advantage policies. ¶ 58, Ex. 2. This "Evidence of Coverage" expressly authorizes Humana's insureds to rely on third-party copay assistance. *E.g.*, Ex. 2 at 122 ("When you add up your out-of-pocket cost, you ***can include*** the payments listed below . . . These payments are <u>also included</u> if they are made on your behalf by ***certain other individuals or organizations***. This includes payments for your drugs made by a friend or relative, [and] by most charities, . . ."") (emphases in original). A 2005 HHS OIG bulletin likewise recognizes that Medicare patients may receive copay assistance from independent charities. ¶ 67. Without adequately alleging a breach of contract, Humana's tortious interference claims should be dismissed. *Bittens* v. *Board of Managers of Octavia Condo.*, 18 N.Y.S.3d. 29, 30 (1st Dep't 2015) (summary judgment).

The Complaint is also deficient because it does not plead that Regeneron had "actual knowledge of the terms of the contract and of the contractual obligation that was allegedly

breached," *State St. Glob. Advisors Tr. Co.* v. *Visbal*, 431 F. Supp. 3d 322, 348 (S.D.N.Y. 2020), which requires Regeneron to know the contractual terms allegedly breached between Humana and specific third parties. Humana alleges that "Regeneron obtained the specific details of those provisions through the EYLEA4U program," ¶ 157, and that "Regeneron understood that the cost-sharing obligations discussed above were terms of contracts that Humana maintained with its members." ¶ 218. But Humana provides no "specifics" beyond "mere speculation" that Regeneron had actual knowledge of the purported provisions with which Humana alleges Regeneron tortiously interfered. This deficiency is fatal to Humana's claim. As courts have held, general allegations that the defendant "was made aware" or "was aware" of contract provisions "fall short of the requirements of a tortious-interference claim." *Talon Pro. Servs., LLC* v. *CenterLight Health Sys. Inc.*, 2021 WL 1199430, at *8 (S.D.N.Y. Mar. 30, 2021) (internal citations omitted). But even if Regeneron had knowledge of the contract provisions, it would be *even more confident* that there was no breach of those provisions. As discussed above, Humana's Evidence of Coverage expressly authorizes Humana's insureds to rely on third party copay assistance. Ex. 2 at 122 . It is not possible for Regeneron to have "actual knowledge" of a "contractual obligation that was allegedly breached" where there is in fact no contractual obligation that was breached. *State St. Glob. Advisors Tr. Co.,* 431 F. Supp. at 348.

Finally, because Humana has not alleged tortious interference, its aiding and abetting claim must be dismissed. *Navarra* v. *Marlborough Gallery, Inc.*, 2012 WL 13210272, at *9 (S.D.N.Y. Apr. 4, 2012) ("In order to allege a claim for aiding and abetting a particular tort, there must first be an actionable underlying tort.").

C. The Complaint Does Not State a Claim for Unjust Enrichment.

To plead unjust enrichment, Humana must adequately allege "(1) that the defendant benefitted, (2) at the plaintiff's expense, and (3) that equity and good conscience require

restitution." *Barreto* v. *Westbrae Nat., Inc.*, 2021 WL 76331, at *8 (S.D.N.Y. Jan. 7, 2021). New York law does not permit unjust enrichment as "a catchall cause of action to be used when others fail," and it is "not available where it simply duplicates, or replaces, a conventional contract or tort claim" because "the extent that these [other] claims succeed, the unjust enrichment claim is duplicative; if plaintiffs' other claims are defective, an unjust enrichment claim cannot remedy the defects." *Corsello* v. *Verizon N.Y., Inc.*, 18 N.Y.3d 777, 791 (2012). Rather, an unjust enrichment claim "is available only in unusual situations when, though the defendant has not breached a contract nor committed a recognized tort, circumstances create an equitable obligation running from the defendant to the plaintiff." *Id.* at 790.

No such unusual circumstances exist here. Humana's allegations that Regeneron "voluntarily accepted and retained the payments it has received and the other associated benefits conveyed to it by Humana as a result of Regeneron's scheme," ¶ 265, merely restate the alleged misconduct on which Humana's other claims are based.

Courts routinely dismiss unjust enrichment claims that, as here, merely duplicate other tort claims. *See, e.g.*, *Marini* v. *Adamo*, 644 F. App'x 33, 35–36 (2d Cir. 2016) (dismissing unjust enrichment claim as "duplicative of the common law fraud" claim); *Am. Bio Medica Corp.* v. *Bailey*, 341 F. Supp. 3d 142, 162 (N.D.N.Y. 2018); *Barreto* v. *Westbrae Nat., Inc.*, 2021 WL 76331, at *8 (S.D.N.Y. Jan. 7, 2021).

D. The Complaint Does Not State a Claim Under N.Y. GBL § 349.

The Complaint does not state a claim under New York's consumer protection law, GBL § 349, because the Complaint does not and cannot allege that Humana is a "consumer." While Humana alleges that it is "a *person or consumer* entitled to protection under New York's consumer protection law and other states' consumer protection laws," ¶ 270 (emphasis added), it is not a "consumer," but a multi-hundred billion dollar corporate entity that provides services *to*

consumers. Courts have dismissed Section 349 claims where the alleged misconduct was directed at large, sophisticated businesses. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597, 613–14 (S.D.N.Y. 2005) (health benefit providers could not recover under Section 349 where defendant allegedly misrepresented safety of a drug because the "nature of this marketing effort—communication from one sophisticated business to another—was quite different from that of any promotion aimed directly at diabetes patients"). It is irrelevant that Humana's *policyholders* may be viewed as consumers, because "the fact that consumers were the ultimate end-users [does not] convert the transaction into a consumer transaction." *Black Radio Network, Inc*. v. *NYNEX Corp*., 44 F. Supp. 2d 565, 583 (S.D.N.Y. 1999).

Humana's claim also fails because the alleged conduct is not "consumer-oriented." *Gale* v. *Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 250 (S.D.N.Y. 2013) (Briccetti, J.). Under the statute, "consumer-oriented" means "conduct that potentially affects similarly situated consumers." *SQKFC, Inc.* v. *Bell Atl. TriCon Leasing Corp.*, 84 F.3d 629, 636 (2d Cir. 1996) (internal punctuation omitted). Humana alleges that Regeneron maintained the price of EYLEA through fraud, causing "consumers who did not receive CDF funding, and whose doctors chose (for whatever reason) to prescribe Eylea over Avastin . . . to pay far more for the drug than they would have absent Regeneron's fraud." ¶ 275. This does not constitute "consumer-oriented conduct" under the statute. Where, as here, "the gravamen of the complaint is harm to a business as opposed to the public at large, the business does not have a cognizable cause of action under § 349."[11] The same deficiencies defeat Humana's claims under the other state consumer

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[11] *See also Gucci Am., Inc.* v. *Duty Free, Ltd*., 277 F. Supp. 2d 269, 274 (S.D.N.Y. 2003); *Moshik Nadav Typography LLC* v. *Banana Republic, LLC*, 2021 WL 2403724, at *4 (S.D.N.Y. June 10, 2021) (dismissing claim where "the core of the claim is a dispute between businesses, not harm to consumers.")

protection statutes, ¶ 277.[12] The gravamen of Humana's Complaint is that Humana was harmed by having to reimburse co-pays for EYLEA, not that *consumers* were somehow harmed at the hands of Regeneron. New York's consumer protection statute (like the others) is not designed as or permitted for use as a remedy for such business-oriented harm.

Finally, these claims are deficient because the Complaint does not adequately plead that Regeneron's conduct caused Humana's purported injuries. *See* pp. 25–27, above; *Miller* v. *Wells Fargo Bank, N.A.*, 994 F. Supp. 2d 542, 557 (S.D.N.Y. 2014) (Briccetti, J.).[13]

IV. In the Alternative, the Court Should Stay This Action Pending Resolution of the Nearly Identical DOJ Action.

While the Court should dismiss the Complaint in its entirety for the foregoing reasons, in the alternative, the Court should stay this litigation pending a resolution of the nearly identical—and far more advanced—DOJ Action.

This Court has inherent authority as "part of its general power to administer its docket . . .

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[12] *See, e.g.*, *In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 422–26 (D.N.J. 2018) (dismissing claim under state deceptive trade practice laws of Illinois, Nebraska, and New York); *Sheet Metal Workers Local 441 Health & Welfare Plan* v. *GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 403–19 (E.D. Pa. 2010) (Arizona, Colorado, Michigan, and North Carolina law); *Carriuolo* v. *Gen. Motors Co.*, 823 F.3d 977, 983–84 (11th Cir. 2016) (Florida law); *Kinetic Co.* v. *Medtronic, Inc.*, 672 F. Supp. 2d 933, 945–46 (D. Minn. 2009) (Minnesota law).

[13] *See also Mulligan* v. *Choice Mortg. Corp. USA,* 1998 WL 544431, at *11 (D.N.H. Aug. 11, 1998) (requiring plaintiff to plead causation under N.H. deceptive trade practice law); *Bower* v. *AT&T Mobility, LLC*, 127 Cal. Rptr. 3d 569, 576–78 (Cal. Ct. App. 2011); *Peterson* v. *USAA Life Ins. Co.*, 353 F. Supp. 3d 1099, 1114–15 (D. Colo. 2018), *aff'd*, 814 F. App'x 408 (10th Cir. 2020); *CareerFairs.com* v. *United Bus. Media LLC*, 838 F. Supp. 2d 1316, 1324 (S.D. Fla. 2011); *De Bouse* v. *Bayer AG,* 235 Ill. 2d 544, 554 (Ill. 2009); *Montgomery* v. *Kraft Foods Glob., Inc.,* 2012 WL 6084167, at *7 (W.D. Mich. Dec. 6, 2012), *aff'd,* 822 F.3d 304 (6th Cir. 2016); *Graphic Commc'ns Local 1B Health & Welfare Fund A* v. *CVS Caremark Corp.*, 850 N.W.2d 682, 693 (Minn. 2014); *Kanne* v. *Visa U.S.A. Inc.*, 272 Neb. 489, 500 (Neb. 2006); *Optical Alignment Sys. & Inspection Servs., Inc.* v. *Alignment Servs. of N. Am., Inc.*, 909 F. Supp. 58, 62 (D.N.H. 1995); *Gale* v. *Int'l Bus. Mach. Corp.*, 781 N.Y.S.2d 45, 46 (2nd Dep't 2004); *Gibson* v. *Credit Suisse AG*, 2012 WL 529702, at *26 (D. Idaho Feb. 17, 2012), *report and recommendation adopted in relevant part*, 2012 WL 1253007 (D. Idaho Mar. 30, 2012) (Nevada law); *Bumpers* v. *Community Bank of N. Va.*, 367 N.C. 81 (N.C. 2013).

[to] stay or dismiss a suit that is duplicative of another federal court suit." *Curtis* v. *Citibank, N.A.*, 226 F.3d 133, 138 (2d Cir. 2000). In considering a motion to stay, the courts in this Circuit consider and balance the interests of plaintiffs, defendants, the courts, non-parties, and the public. *Liguori* v. *Wells Fargo Bank, N.A.*, 2020 WL 5370709, at *3 (S.D.N.Y. Sept. 8, 2020) (Briccetti, J.).

A stay of this action would serve the interests of Regeneron, the courts, non-parties, and the public by avoiding duplicative and wasteful litigation in two different federal courts. Both actions arise from the same set of facts and, in both cases, Humana and DOJ (respectively) will need to prove that Regeneron's donations to CDF were unlawful. Litigating, in parallel, two cases involving substantially identical facts and related legal issues would impose substantial costs on Regeneron and the courts. *See, e.g.*, *Readick* v. *Avis Budget Grp., Inc.*, 2014 WL 1683799, at *5 (S.D.N.Y. Apr. 28, 2014) ("Unless a stay is granted, [the defendant] will be forced to engage in potentially duplicative and costly discovery. To the extent [the other pending action] disposes of some or all of Plaintiff's claims, discovery in [this action] will serve little or no purpose."). As one court reasoned in similar circumstances, a stay is appropriate because

> the parties here have not engaged in any substantial discovery, nor any dispositive motions[;] . . . a Rule 16 conference has yet to take place[;] . . . expert reports have not been exchanged and no discovery deadlines have been set . . . [u]nlike in the [other pending] litigation where substantial amounts of time and expense have been invested in preparation by the parties . . .

HMT, Inc. v. *Bell BCI Co.*, 2007 WL 295328, at *2 (W.D.N.Y. Jan. 30, 2007).

Courts have stayed duplicative proceedings in similar circumstances. In *Simms et al.* v. *Philip Morris, Inc., et al.*, Case No. 01-1107 (GK) (D.D.C. July 7, 2003), private plaintiffs brought suit based on allegations in a pending litigation by DOJ. The court noted the "substantial overlap of both factual and legal issues between the two cases," and concluded that a stay was "necessary to avoid diversion of the Court's and Defendants' resources from the DOJ case." Ex.

34 at 2–4. The court also noted that "[m]ost importantly, the Government represents the public interest in the DOJ case." *Id.* at 4; *see also Mortland* v. *OhioHealth Corp.*, 2007 WL 9728545, at *2 (S.D. Ohio Feb. 7, 2007) (granting stay where "[m]uch if not all of the remaining discovery and expert contributions will be wholly duplicative, and the DOJ investigation is further along than discovery in this case, which is still much in its preliminary stages.").

Granting a stay may also narrow the legal issues in controversy. In *Simms*, the court reasoned that a stay was appropriate, in part, because "rulings in the DOJ case are virtually certain to 'illuminate or resolve' many issues which will arise in [*Simms*]." Ex. 34 at 2.[14]

Humana would suffer no prejudice from a stay, because "delay alone does not establish prejudice." *Liguori*, 2020 WL 5370709, at *4 (Briccetti, J.). Humana's lack of diligence in pursuing its claims underscores the absence of any prejudice, as it has known since at least February 2017 that DOJ was investigating Regeneron regarding its donations to CDF for EYLEA patients. Yet Humana took no action for nearly four and a half years after the investigation was announced. Instead, it continued, as it alleges, to make payments for EYLEA that it now claims were improper, fraudulent, and in breach of its own policies. The Court need not treat this litigation as urgent when Humana itself has not done so.

CONCLUSION

For the foregoing reasons, the Complaint should be dismissed in its entirety. In the alternative, this action should be stayed pending a resolution of the DOJ Action.

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[14] *See also HMT, Inc.*, 2007 WL 295328, at *2–3 (granting stay because "resolution of the [other pending] litigation will more than likely narrow the issues before this Court and ultimately save the parties and the Court from a needless or duplicative expenditure of resources."); *Sensient Colors, Inc.* v. *Kohnstamm*, 2008 WL 11456113, at *2 (S.D.N.Y. July 7, 2008) (granting stay because parallel case "may not settle every question of fact and law . . . but in all likelihood it will settle many and simplify them all") (internal citations omitted); *Specrite Design, LLC* v. *Elli N.Y. Design Corp.*, 2017 WL 3105859, at *6 (S.D.N.Y. July 20, 2017).

Dated: New York, New York
September 27, 2021

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APPENDIX A – Applicable Limitations Periods

Claim	Limitations Period	
Count I: Fraudulent Concealment & Fraud [15]	6 years or 2 years from when plaintiff discovered or should have discovered the fraud	
Counts II & III: Tortious Interference with Contract & Aiding and Abetting Tortious Conduct [16]	3 years	
Counts IV & V: Civil RICO & RICO Conspiracy [17]	4 years from when plaintiff discovered or should have discovered the RICO injury	
Count VI: Unjust Enrichment [18]	6 years	
Count VII: Violation of New York General Business Law § 349 & Other State Deceptive Trade Practices Laws [19]	Arizona	1 year based on inquiry notice
	California	4 years
	Colorado	3 years based on inquiry notice
	Florida	4 years or 2 years from last transaction
	Illinois	3 years
	Michigan	6 years or 1 year from last transaction
	Minnesota	6 years
	Nebraska	4 years
	Nevada	4 years based on inquiry notice
	New Hampshire	3 years based on inquiry notice
	New York	3 years
	North Carolina	4 years based on inquiry notice
Count VIII: Violation of Three State Insurance Fraud Laws[20]	Kentucky	5 years based on inquiry notice
	Pennsylvania	2 years based on inquiry notice
	Tennessee	5 years based on inquiry notice

[15] N.Y. C.P.L.R. 213(8).

[16] N.Y. C.P.L.R. 214(4).

[17] *Koch* v. *Christie's Int'l PLC*, 699 F.3d 141, 148 (2d Cir. 2012).

[18] N.Y. C.P.L.R. 213(2).

[19] N.Y. C.P.L.R. 214(2); *Erickson* v. *Ditech Fin., LLC*, 2017 WL 1508596, at *13 (D. Ariz. Apr. 27, 2017) (citing A.R.S. § 12-541(5)); Cal. Bus. & Prof. Code § 17208; Colo. Rev. Stat. § 6-1-115; Fla. Stat. § 501.207(5); 815 Ill. Comp. Stat. Ann. 505/10a(e); Mich. Comp. Laws § 445.910(5); Minn. Stat. § 541.05; Neb. Rev. Stat. Ann. § 59-1612; Nev. Rev. Stat. § 11.190(3)(d); N.H. Rev. Stat. Ann. § 508:4; *Dreamstreet Investments, Inc.* v. *MidCountry Bank*, 842 F.3d 825 (2016) (citing N.C. Gen. Stat. Ann. § 75-16.2).

[20] Ky. Rev. Stat. Ann. § 413.120(2); 42 Pa.C.S. § 5524; Tenn. Code Ann. § 56-53-107(e).

APPENDIX B – Count VII Grounds for Dismissal

	Barred by Last Allegations of Misconduct More Than Six Years Ago	Barred by Humana's Inquiry Notice	Barred by Inadequate Allegations that Humana is a Consumer	Barred by Inadequate Allegations of Causation
Arizona Ariz. Rev. Stat. Ann. § 44-1521, *et seq.*		✓	✓	✓
California Cal. Bus. & Prof. Code § 17200, *et seq.*	✓			✓
Colorado Colo. Rev. Stat. § 6-1-101, *et seq.*		✓	✓	✓
Florida Fla. Stat. § 501.201, *et seq*.	✓		✓	✓
Illinois 815 Ill. Comp. Stat. 505/1, *et seq.*	✓		✓	✓
Michigan Mich. Comp. Laws § 445.901, *et seq.*	✓		✓	✓
Minnesota Minn. Stat. § 325F.68, *et seq.*	✓		✓	✓
Nebraska Neb. Rev. Stat. § 59-1601, *et seq.*	✓		✓	✓
Nevada Nev. Rev. Stat. § 41.600, *et seq.*		✓		✓
New Hampshire N.H. Rev. Stat. Ann. § 358-A:1, *et seq.*		✓		✓
New York General Business Law § 349	✓		✓	✓
North Carolina N.C. Gen. Stat. § 75-1.1, *et seq.*		✓	✓	✓